510(k) Summary of Safety and Effectiveness

MAY 14 2009

SUBMITTER: Surgical Devices, a global business unit
of Tyco Healthcare Group LP (d/b/a Covidien)
60 Middletown Avenue
North Haven, CT 06473
Tel. No.: (203) 492-6060

CONTACT PERSON: Jennifer Brennan
Manager, Regulatory Affairs

DATE PREPARED: January 19, 2008

TRADE/PROPRIETARY NAME: Autosuture™ Protack, Autosuture™ TACKER™ System, Absorbatack™ Absorbable Fixation Devices

COMMON/USUAL NAME: Surgical Stapler with Implantable Staple

CLASSIFICATION NAME: Staple, Implantable

PREDICATE DEVICE(S): Autosuture™ Protack™ (K963999),
Autosuture™ TACKER™ System (K944415),
Absorbatack™ Absorbable Fixation Devices (K071920)

DEVICE DESCRIPTION:

Autosuture™ Protack™: The Autosuture™ Protack 5 mm instrument contains 30 titanium helical fasteners. The diameter of the fastener measures approximately 4 mm and the length is approximately 3.8 mm. The instrument is designed for introduction and use through an appropriately sized trocar sleeve or larger with the use of a converter. The overall length of the shaft is approximately 35.5 cm.

Autosuture™ TACKER™ System: The Autosuture™ TACKER™ System is packaged in 4 different product configurations as specified on the product package. The Autosuture™ TACKER™ System contains the following products: The **Autosuture™ TACKER™ delivery device,** which contains 20 titanium helical fasteners and is designed to be used with the Autosuture™ TACKER™ reusable handle. The Autosuture™ TACKER™ reusable handle is packaged sterile and may be resterilized four (4) times for a total of five (5) uses. The **Autosuture™ STAT TACK™** single use instrument is designed to deliver 15 helical fasteners. The helical fastener size is approximately 3.9 mm in diameter by 4 mm long.

Absorbatack™ Absorbable Fixation Devices: The Absorbatack™ Absorbable Fixation Device is a sterile single use device for fixation of prosthetic material, such as mesh, to soft tissue. The tack is constructed of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid. The device is offered with 5, 10, or 20 absorbable tacks.

INTENDED USE:

Autosuture™ Protack™: The Autosuture™ Protack™ 5 mm instrument has application in endoscopic surgery procedures for fixation of prosthetic material and approximation of tissue in various surgical specialties, such as the repair of hernial defects.

Autosuture™ TACKER™ System: The Autosuture™ TACKER™ System is indicated to affix prosthetic material or approximate tissue in a variety of endoscopic or other surgical procedures.

	Absorbatack™ Absorbable Fixation Devices: The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia repair.
TECHNOLOGICAL CHARACTERISTICS:	**The Autosuture™ Protack™** is identical to the predicate device. **The Autosuture™ TACKER™ System** is identical to the predicate device. **The Absorbatack™ Absorbable Fixation Device** is identical to the predicate device.
MATERIALS:	The Autosuture™ Protack, Autosuture™ TACKER™ System, Absorbatack™ Absorbable Fixation Devices are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	There have been no changes to the Autosuture™ Protack, Autosuture™ TACKER™ System, Absorbatack™ Absorbable Fixation Devices. Performance testing is not applicable to this 510(k) – Changes Being Effected, since only contraindications are being added.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2009

Covidien
% Ms. Jennifer Brennan
Manager Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K090470
Trade/Device Name: Autosuture™ Protack, Autosuture™ TACKER™ System
Absorbatack™ Absorbable Fixation Devices
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW, GDW
Dated: February 4, 2009
Received: February 27, 2009

Dear Ms. Brennan:

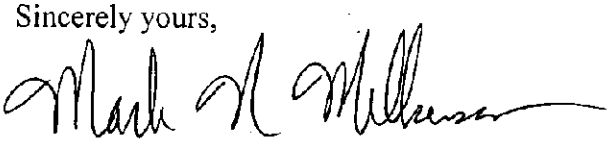
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090470

Device Name: **Autosuture™ Protack, Autosuture™ TACKER™ System Absorbatack™ Absorbable Fixation Devices**

Indications For Use

Autosuture™ Protack: The Auto Suture™ Protack™ 5mm instrument has application in endoscopic surgery procedures for fixation of prosthetic material and approximation of tissue in various surgical specialties, such as the repair of hernial defects.

Autosuture™ TACKER™ System: The Auto Suture™ TACKER™ System is indicated to affix prosthetic material or approximate tissue in a variety of endoscopic or other surgical procedures.

Absorbatack™ Absorbable Fixation Devices: The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia
repair.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090470